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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/536,501

08/09/2005

Kazunori Muta

28727U

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20529 7590 04/24/2009
THE NATH LAW GROUP
112 South West Street
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EXAMINER

ORWIG, KEVIN S

ART UNIT

PAPER NUMBER

1611

MAIL DATE

DELIVERY MODE

04/24/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/536,501	Applicant(s) MUTA ET AL.	
	Examiner Kevin S. Orwig	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☒ Claim(s) 4-7 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Aug. 9, 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/25/05, 6/14/05, 8/30/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

Claims 1-7 are currently pending and are the subject of this Office Action. This is the first Office Action on the merits of the claims. The most recent claim set, filed Aug. 9, 2005 will be examined further on the merits of the claims.

Election/Restrictions

In the response of dated Feb. 26, 2009, applicants elected the following species of warming material: capsicum extract (i.e. hot pepper extract). This election was made without traverse. In the response to the election requirement, applicants have stated that claims 1-7 read on the elected species.

Information Disclosure Statement

The references provided on the information disclosure statement(s) were considered and have been made of record.

Claim Objections

Claims 4-7 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only and cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by MANABE (JP 2002-029993; Published Jan. 29, 2002; 1st foreign reference on IDS dated May 25, 2005; English translation provided herein).

1. Manabe discloses a patch comprising a warming substance and having low skin irritation qualities, which is the object of Manabe's invention (pars. [0003] and [0004]; claim 4). Manabe teaches that the warming material component is a capsaicinoid of hot pepper origin, including hot pepper extract (pars. [0010] and [0011]). Additionally, Manabe teaches that other components including water soluble adhesive polymers, l-menthol, and polyethylene glycol are suitable for use in the adhesive base of the invention and that the adhesive base is present on a support (pars. [0015]-[0017] and [0019]). Manabe exemplifies warming patches comprising 0.01% hot pepper extract, 0.25% l-menthol, and 4.0% polyethylene glycol in an adhesive base composition spread on a support (Example 1, par. [0022]; Example 12, par. [0028]), thus anticipating claims 1-3.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over IIDA (JP 1991-161435; Published Jul. 11, 1991; 2nd Foreign reference on IDS dated May 25, 2005; English translation provided herein).

2. Iida discloses a patch that suppresses skin irritation (p. 3, middle paragraph). Iida exemplifies patches that comprise 0.2% capsicum extract, 0.5-1.0% l-menthol, and 1.0-10% polyethylene oxide (i.e. polyethylene glycol) (p. 14, Table 6). Thus, the only

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difference between lida and the instant claims is that lida does not exemplify a composition comprising each of these components together and does not teach capsicum extract in the instantly claimed percent range.

3. Nonetheless, it is well within the skill of the ordinary artisan to combine or rearrange elements known in the prior art for a given purpose. For example, if an artisan wanted to make a patch of lida's Example 10 (Table 6) having warming qualities, one would be motivated to add capsicum extract to the patch composition as taught by lida, thus providing a warming composition as known in the art. The amount of warming material is clearly a result-effective variable that would be optimized by an ordinary artisan by routine experimentation based on the desired level of warming effect.

4. Regarding the instantly claimed percentage ranges, the MPEP states, "Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)". In the instant case, there is no evidence of record to indicate that the claimed weight ranges and amounts for the various components are critical to the general function of the invention. For instance, paragraph [0020] of the instant specification clearly states that the amount of the warming material is not limited to the ranges disclosed as preferable. Likewise, paragraph [0022] of the instant specification states

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that the amount of l-menthol is not particularly limited. Claims 1-3 are rendered obvious over lida.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over MORI (JP 1981-010888; Published Oct. 11, 1981; English translation provided herein) in view of WEISS (U.S. 3,944,663; Issued Mar. 16, 1976) and OKAMOTO (JP 06-256183; Published Sep. 13, 1994; 2nd foreign reference on IDS dated Jun. 14, 2005).

5. Mori discloses a heat stimulating patch with low skin irritation (all of page 2). Mori teaches that capsicum extract is a useful heat stimulating component for the invention (p. 4, 3rd paragraph). Mori exemplifies patch compositions having capsicum extract and l-menthol (p. 5, Examples 1 and 3) and teaches the use of 10-70% polyethylene glycol (p. 3, last paragraph). Thus, the only difference between Mori and

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the instant claims is that Mori does not exemplify a composition comprising each of these components and does not teach capsicum extract in the instantly claimed percent range.

6. However, the skin irritation reducing properties of polyethylene glycol were recognized decades ago. As evidence, Weiss teaches that homopolymers of ethylene oxide (i.e. polyethylene glycol), for example, in concentrations up to 5% by weight, act to reduce skin irritation (abstract; col. 1, lines 54-58; col. 4, lines 60-63). Furthermore Okamoto discloses the use of polyoxyalkylene glycols as an irritation-reducing agent in a patch containing l-menthol and an irritation inducing NSAID (abstract).

7. In light of these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to have selected polyethylene glycol from the list of polyatomic alcohols taught by Mori to provide a warming patch with less skin irritation, which is precisely in line with the object of Mori's invention. One would have been motivated to do so since polyethylene glycol was known to reduce skin irritation per the teachings of Weiss and Okamoto. Thus, the artisan would have had a high expectation of success in selecting polyethylene glycol for use in Mori's invention.

8. Furthermore, the amount of warming material is clearly a result-effective variable that would be optimized by an ordinary artisan by routine experimentation based on the desired level of warming effect. Regarding the instantly claimed percentage ranges, the MPEP states, "Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions

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of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)". In the instant case, there is no evidence of record to indicate that the claimed weight ranges and amounts for the various components are critical to the general function of the invention. For instance, paragraph [0020] of the instant specification clearly states that the amount of the warming material is not limited to the ranges disclosed as preferable. Likewise, paragraph [0022] of the instant specification states that the amount of l-menthol is not particularly limited. Claims 1-3 are rendered obvious over lida.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Conclusion

Claims 1-3 are rejected. Claims 4-7 are objected to. No claims are currently allowable.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin S. Orwig whose telephone number is (571)270-5869. The examiner can normally be reached Monday-Friday 7:00 am-4:00 pm (with alternate Fridays off). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached Monday-Friday 8:00 am-5:00 pm at (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KSO

/David J Blanchard/

Primary Examiner, Art Unit 1643